



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Biomedical Engineering Society and FDA Frontiers in Medical Devices: Innovations in Modeling and Simulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Public Conference

The Food and Drug Administration (FDA) in co-sponsorship with the Biomedical Engineering Society (BMES) is announcing a public conference entitled “Frontiers in Medical Devices: Innovations in Modeling and Simulation”. The purpose of this conference is to provide a forum to discuss strategies to effectively utilize computational modeling and simulation in the development and evaluation of medical devices.

Date and Time: The conference will be held on May 18 through 20, 2015, from 8 a.m. to 6 p.m.

Location: The public conference will be held at the Marriott Inn and Conference Center, University of Maryland, 3501 University Blvd. East, Hyattsville, MD 20783.

Contact Person: Donna R. Lochner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3220, Silver Spring, MD 20993, 301-796-6309, Donna.Lochner@fda.hhs.gov.

Registration: To register for the public conference please visit FDA's Medical Devices News, Events, Workshops, and Conferences calendar at <http://www.bmes.org/meddevicesconference>. There is a registration fee to attend the public conference to cover the expenses, and attendees must register in advance. The fees vary depending upon membership status in BMES, and include BMES members (\$450), non-BMES members (includes 1 year BMES membership) (\$600), and Government rate (BMES memberships and meals are not included) (\$250). Students will be offered a discounted fee of \$300 (BMES member) or \$350 (non-BMES member) (includes 1 year BMES membership). A full listing of the registration fees can be found on the Web site listed. Although the facilities are spacious, registration will be on a first-come, first-served basis.

If you need special accommodations due to a disability, please contact Betse Lyons at Betse@bmes.org or 301-459-1999, 8201 Corporate Drive, Suite 1125, Landover, MD 20785-2224, FAX: 301-459-2444, no later than May 4, 2015.

To register for the public conference, please visit BMES Frontiers in Medical Devices registration page at <http://bmes.org/meddevicesregistration>. Those without Internet access should contact Betse Lyons at 301-459-1999 to register.

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Devices and Radiological Health (CDRH) believes that computer modeling and simulation (M&S) has the potential to substantially augment traditional models used to evaluate medical devices; i.e., animal, bench, and human models, and to accelerate and streamline the total product life cycle of a medical device. The use of computer models to

simulate multiple use conditions and to visualize and display complex processes and data can revolutionize the way medical outcomes and medical devices are understood. Non-proprietary computer models could benchmark device performance, yet lack of access to biomedical data to construct the models and rigorous methods to validate the models limit their credibility and use. To foster good science for M&S in the medical device community, CDRH needs to leverage the expertise in industry and academia to advance M&S for regulatory uses.

II. Topics for Discussion at the Public Workshop

A large number of issues will be discussed at the conference with the overall theme being the application of modeling and simulation for medical devices at different stages in the total product life cycle. Topics include, but are not limited to the following:

- Model foundations for device design ideation;
- concept development and design optimization;
- modeling for robust design;
- design verification and validation;
- patient specific design;
- integration of modeling with clinical studies;
- modeling and device commercialization.

This public workshop may also form the basis for future discussions related to computer modeling and simulation that could benefit U.S. public health.

Dated: March 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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